

DETAILED ACTION

Previous Rejections

Applicants' arguments, filed 2/15/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 23 is objected to because of the following informalities: misspelled words in the claims. See "propy" paraben. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 depends from claim 18 and recites "wherein the viscid substance is starch or polymer". There is insufficient antecedent basis for this limitation in the claim because claim 18 does not recite a viscid substance.

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Claim 21 depends from claim 18 and recites "wherein the polymer.....". There is insufficient antecedent basis for this limitation in the claim because claim 18 does not recite a polymer.

Claim 23 depends from claim 18 and recites "wherein the gel". There is insufficient antecedent basis for this limitation in the claim because claim 18 does not recite a gel.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "viscid" in claims 19 and 20 is a relative term which renders the claim indefinite. The term "viscid" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 18-19 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellison et al. (US 2002/0183385).

Ellison et al. discloses arsenic substances such as arsenic trioxide in a pharmaceutical carrier for the treatment of skin neoplasms (see "squamous cell carcinoma" "basal cell carcinoma" and "melanoma", [0051]). Various dosage forms for topical administration are disclosed including creams, ointments and pastes ([0049]). Ellison et al also teaches that when there is poor solubility in aqueous solvents the arsenic substance may be formulated for administration through routes such as topical with a "viscid substance" (see "viscous material" [0062]). Ellison et al teaches the preferred dose is between 0.5 mg to about 70 mg ([0073]).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 18, 22 and 24-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Lai et al. (Anti-Cancer Drugs (2003) vol. 14, pages 825-828).

Lai et al. disclose a topical gel pharmaceutical composition comprising arsenic trioxide for the treatment of skin neoplasm such as those having a cutaneous metastatic breast cancer (see from the first full paragraph on right column of page 825 to the

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second paragraph on left column of page 826). The arsenic trioxide is present in the gel at 0.05% (page 826, left column, second paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellison et al. (US 2002/0183385), in view of Deckner et al. (US Patent No. 4,847, 267).

Ellison et al. as discussed above and differs from the instant claims insofar as it does not disclose the specific "viscid substances" of claims 20 and 21 and specific formulation of Applicant's claim 23

Deckner et al teaches topical formulations in the form of a lotion, cream, liquid or ointment from about 1 to 10% emulsifiers (col. 2, line 17) such as polyethylene glycol

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(col. Lines 8-15); from about 0.05 to about 4% of gelling agents (col. 2, lines 19-20) such as Carbomer 940, (col. 3, line 21); and from about 0.05 to about 2% preservative (col. 2, lines 28-30) such as propylparaben (col. 2, line 64). Additionally Deckner et al. teaches that the term "ointment" is inclusive of a gel (col. 5, lines 44-46).

Deckner et al. differs insofar as it does not teach arsenic trioxide.

Accordingly, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See *Sinclair and Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 YSPQ 297 (1945). See also *In re Leshin* 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Accordingly, it would have been obvious to have used various known gel forming components in forming the primary reference gels and ointments, (e.g. carbomer 940, PEG, propylparaben), since those components are well known for use in gels as taught by the secondary reference.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-F 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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